UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,517	07/09/2001	J. Jeffrey Seilhamer	219002025213	7422

25225 7590 10/15/2003

MORRISON & FOERSTER LLP
3811 VALLEY CENTRE DRIVE
SUITE 500
SAN DIEGO, CA 92130-2332

EXAMINER	
EPPS FORD, JANET L	

ART UNIT	PAPER NUMBER
1635	19

DATE MAILED: 10/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/902,517	SEILHAMER ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Ford, Ph.D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32 and 41-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32 and 41-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Arguments

1. Applicant's argument's with respect to the rejection of claims 32 and 41-44 under 35 U.S.C. 103(a) as being unpatentable over Sudoh et al. in view of Hirth et al. have been fully considered, but are moot in view of the new grounds for rejection.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102 or § 103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claim 32 and 41-44 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hirth et al. as evidenced by Sudoh et al. Claim 32 is drawn to antibodies useful for immunoassays to detect a peptide which peptide comprises human brain natriuretic peptide of the formula: Ser-Pro-Lys-Met-Val-Gln-Gly-Ser-Gly-Cys-Phe-Gly-Arg-Lys-Met-Asp-Arg-Ile-Ser-Ser-Ser-Ser-Gly-Leu-Gly-Cys-Lys-Val-Leu-Arg-Arg-His, or a C-terminal amide thereof. Claims 41-44 are drawn to the antibodies of claim 32, wherein said antibodies are monoclonal, further comprise a label, methods to perform an immunoassay comprise the use of the antibodies of claim 32, and a kit for conducting an immunoassay.

Hirth et al. disclose monoclonal antibodies targeting ***human*** and rat atrial natriuretic peptides (see col. 4-5, Example 1). Note that human alpha-ANP was used as an antigen to immunize mice used to isolate the antibodies, see col. 4, line 41. Additionally, Hirth et al. describe methods for using these antibodies for the determination of the levels of ANPs in biological fluids, isolating ANPs using chromatography, and for immunoassays (see col. 2, lines 51-59). Hirth provides methods also for the preparation of monoclonal antibodies against natriuretic peptides of ***humans*** and rats, see Example 1 (col. 4-5).

Sudoh et al. discloses the amino acid sequence of human alpha-ANP, see Figure 2. The amino acid sequence of human α-ANP shares multiple regions of identity with the amino acid sequence of porcine brain natriuretic peptide. Absent evidence to the contrary, the monoclonal antibodies targeting human α-ANP described in Hirth et al. would also be expected to be useful to detect the presence of human brain natriuretic peptide due to the observation that the amino acid sequence of human BNP shares multiple regions of identity with the amino acid sequence of human α-ANP. These regions of identity between human BNP and human α-ANP correspond to the same regions of identity between human α-ANP and porcine BNP, see Figure 2 of Sudoh et al. and the following:

human α-ANP: SLRRSS **CFGGRMDRI**GAQ**SGLGC**NSF**R**Y
S CFG + MDRI + SGLGC R
human BNP: SPKMVQGSG**CFGRKMDRI**SS S **SGLGC**KVL**R**

Absent evidence to the contrary, since antibodies targeting human α-ANP were useful to detect the presence of porcine BNP, in a different species and tissue, one of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success to detect

the presence of human BNP in a sample using the monoclonal antibodies targeting human α-ANP disclosed by Hirth et al.

See also MPEP § 2112.01, which states "[W]here the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established." In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claim 32 is rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sudoh et al.

Sudoh et al. disclose antibodies and their use thereof in an immunoassay to identify the presence of atrial natriuretic peptide (ANP) in mammalian tissue. Sudoh et al. teach the identification of "ANP-like" immunoreactivity present in brain extracts from porcine brain tissue (see Figure 1). Identifying fractions with "ANP-like" immunoreactivity (using anti-rat ANP) and further testing of these fractions for relaxant activity allowed Sudoh et al. to further characterize the "ANP-like" activity of these fractions (see Figure 1a). Further purification of fractions with "ANP-like" activity allowed for the identification of a new natriuretic peptide in porcine brain

(pBNP). Additionally, Sudoh et al. disclose the amino acid sequence of porcine brain natriuretic peptide (See Figure 2b). Sudoh et al. implicate pBNP in the regulation of physiological functions such as water intake and salt appetite (see page 80, 2nd paragraph). Additionally, Sudoh et al. speculates that it is probable that BNP is also present in other organs, such as heart, wherein it may function in concert with ANP to maintain the homeostatic balance of body fluid (see page 80, 3rd paragraph).

Absent evidence to the contrary, the antibodies used in the immunoassay to identify porcine brain natriuretic peptide would also be useful for immunoassays to detect a peptide which comprises human brain natriuretic peptide according to the present invention. One of ordinary skill in the art at the time the invention was made, would have had a reasonable expectation of success for using the antibodies of Sudoh et al. to detect human brain natriuretic peptide due to the significant level of homology between human brain natriuretic peptide and the human alpha atrial natriuretic peptide (human α-ANP). Moreover, the human α-ANP antibodies were useful in detecting natriuretic peptide in other species, and tissues, specifically porcine brain natriuretic peptide, which also shares significant sequence homology with human α-ANP.

See also MPEP § 2112.01, which states "[W]here the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established." In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 9:00AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L. Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE
October 9, 2003